

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR  
SYSTEMS PRODUCTS LIABILITY  
LITIGATION

Master File No. 2:12-MD-02327  
MDL 2327

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ETHICON WAVE 3 CASES LISTED IN  
EXHIBIT A

JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE TO  
PLAINTIFFS' MOTION TO LIMIT THE GENERAL OPINIONS  
OF DEFENSE EXPERT WENXIN ZHENG, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") hereby respond in opposition to Plaintiffs' Motion to Limit the General Opinions of Defense Expert Wenxin Zheng, M.D. [ECF Nos. 2834 and 2835] as follows:

Dr. Wenxin Zheng, M.D., is a gynecologic pathologist with over two decades of professional experience. Mot. Ex. E, Zheng General Report ("Report") at 1. He completed a fellowship in gynecologic pathology in 1996, after which he served on the pathology and OB/GYN faculty at multiple medical schools. *Id.* He is currently the Chief of Gynecologic Pathology at the University of Texas Southwestern Medical Center in Dallas, as well as a professor of pathology and professor of obstetrics/gynecology, with a professorship in cancer research. *Id.* His primary areas of research include gynecologic oncology, with a focus on carcinogenesis. *Id.*; Mot. Ex. C, Zheng CV, at 7–10. He has authored, or co-authored, over 160 peer-reviewed publications in the fields of gynecologic pathology and oncology. *Id.* at 18–31; Mot. Ex. E, Report at 2. His professional experience includes the pathological examination over a hundred vaginal mesh specimens. *Id.* at 2; Mot. Ex. A, Zheng 4/3/14 Dep. 24:16–25:10.

Despite Dr. Zheng's extensive education, training, research, and professional experience in the fields of pathology, gynecology, and oncology, Plaintiffs attack his qualifications to offer several of his opinions. This attack is primarily based on a selective reading of Dr. Zheng's prior depositions and an overly broad reading of this Court's rulings in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D.W. Va. 2014). In *Huskey*, Ethicon conceded that Dr. Zheng would not offer several specific opinions. *Id.* at 732. The Court noted, however, that these concessions were "limited to the precise statements identified in the plaintiffs' motions" and that the Court's "ruling does not exclude testimony outside the literal scope of these statements." *Id.* at 734 n.7. Thus, the concessions in *Huskey* were far more limited than what the Plaintiffs claim.

As explained below, Dr. Zheng's opinions disclosed in the Wave 3 cases are clearly within his areas of expertise and do not fall within the concessions identified in *Huskey*. Although Plaintiffs try to cast these opinions as "materials" or "clinical" opinions, they are clearly opinions that Dr. Zheng is qualified to offer based on both his general pathology background and his years of research and study in the fields of gynecologic pathology and oncology. For the reasons stated below, the Court should deny Plaintiffs' Motion in its entirety.

**I. Dr. Zheng Is Qualified to Offer the "Materials" and "Clinical" Opinions Disclosed in His Report, as These Opinions Fall Within the Scope of His Expertise.**

Plaintiffs attack Dr. Zheng's qualifications to offer the following general opinions:

- (i) "the TVT meshes produce a limited foreign body response";
- (ii) "the TVT meshes create 'appropriate tissue integration'";
- (iii) "the TVT does not 'potentiate infection due to its material properties'";
- (iv) "fibrosis and scar plate formation occurs 'normally' in the majority of implanted TVT and TVT-O meshes";
- (v) "the mesh does not contract in vivo";
- (vi) "there is little or no correlation between implantation of the TVT and pain"; and

(vii) “there is no evidence that the mesh is carcinogenic.”

Pl.’s Mem. at 7–8.<sup>1</sup> Plaintiffs argue that Dr. Zheng has conceded that he is not a materials expert and that opinions (i), (ii), (iv), (v), and (vii) are “materials” opinions beyond the scope of his qualifications. *Id.* at 7. Similarly, Plaintiffs claim that opinions (iii) and (vi) are clinical opinions that Dr. Zheng testified he is unqualified to offer. *Id.* at 8.

Plaintiffs’ arguments misconstrue the scope of Dr. Zheng’s opinions and ignore Dr. Zheng’s actual qualification. Instead, Plaintiffs rely on a selective reading of Dr. Zheng’s prior depositions and this Court’s prior ruling in *Huskey*. An actual analysis of Dr. Zheng’s training and experience shows that he is qualified to offer all of these opinions.

**A. Opinions (i) Through (v) are Classic Pathology Opinions Within the Scope of Dr. Zheng’s Expertise.**

Plaintiffs attempt to portray opinions (i) through (v) as “materials” or “clinical” opinions that are beyond the scope of Dr. Zheng’s qualifications. However, these opinions are all classical pathology opinions that Dr. Zheng and other clinical pathologists are generally qualified to offer.

As this Court has noted, a clinical pathologist will, in general, “be knowledgeable in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies.” *Frankum v. Bos. Sci. Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at \*24 (S.D.W. Va. May 1, 2015) (quoting 33 Am. Jur. Trials 467 § 17 (1986)). Dr. Zheng’s opinions about foreign body response, tissue integration, infection, scar formation, and mesh contraction all fall squarely within these areas of expertise that pathologists generally possess. *See, e.g., Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 570070, at \*5 (S.D.W. Va. Feb. 11, 2015) (finding pathologist qualified to offer opinions about “pathology of mesh explants, which includes an analysis of the foreign body response and how a wound heals around mesh”); *Tyree*

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<sup>1</sup> For consistency and ease of reference, Ethicon has numbered these opinions the same way as in Plaintiffs’ Memorandum and in Dr. Zheng’s general report.

*v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 528–29 (S.D.W. Va. 2014) (finding clinical pathologist qualified to offer opinions about mesh degradation, shrinkage, and migration). Thus, Dr. Zheng is clearly qualified to offer opinions (i) through (v), which all deal with topics squarely within the realm of clinical pathology.

By selectively quoting Dr. Zheng’s statements about the scope of his expertise, Plaintiffs are making the same arguments this Court rejected with respect to Dr. Marshall Austin in *Wise*. In that case, the defendant argued that Dr. Austin was not qualified “to offer opinions on wound healing, the foreign body response, and contraction of tissue around a foreign body” based on Dr. Austin’s concession at his deposition that he was not an expert on “contraction of meshes.” *Wise*, 2015 WL 570070, at \*5. The Court rejected this argument, noting that the deposition testimony “does not overcome Dr. Austin’s undeniable expertise as a pathologist. His training and experience in this field equips him to examine tissue and to opine about the tissue’s pathology, including its reactions with other present substances, such as mesh.” *Id.*

Similarly, Dr. Zheng’s concession that he is not an expert in materials or clinical diagnosis does not render him unqualified to offer opinions (i) through (v). These opinions concern the examination of tissue and tissue reaction, which is undeniably within the scope Dr. Zheng’s expertise as a gynecologic pathologist.

**B. Dr. Zheng’s Pain Opinions, as Disclosed in His Report, Are Within the Realm of Pathology and Do Not Fall Within the Scope of the Opinions Excluded in *Huskey*.**

With respect to opinion (vi), the Plaintiffs mischaracterize Dr. Zheng’s opinions to try to bring them within the scope of the Court’s ruling in *Huskey*. In *Huskey*, the Court found that Dr. Zheng was “not qualified to opine whether transvaginal mesh devices cause pain.” 29 F. Supp. 3d at 732–33. However, Dr. Zheng is not offering a clinical opinion about whether mesh devices cause pain. Instead, Dr. Zheng’s report explains that his opinion is that, absent specific findings

of neuromas or nerve abnormalities, it is impossible for any pathologist to correlate pathological findings with pain due to a mesh implant. *See* Mot. Ex. E, Report at 9–10. This is *not* a “clinical” opinion; it is a pathology opinion concerning the limits of correlations that can be drawn from a pathological examination.

Dr. Zheng’s opinion is based on his education, training, and experience as a pathologist and his review of literature. Dr. Zheng cites several studies concerning rates of pain following implantation of TVT and TVT-O, including a study that analyzed the correlation between pain and pathological observations of inflammation, fibrosis, and foreign body reaction. *Id.* This study specifically found no positive correlation between these pathological findings and clinical complaints of pain. *Id.* Dr. Zheng explains, based on his personal experience and his literature review, that “pathologists cannot look at tissue under the microscope and attribute symptoms such as pain to inflammation, fibrosis, or foreign body reaction.” *Id.* at 10. Dr. Zheng similarly explains that “[w]ithout evidence of nerve abnormality, finding nerve fibers in vaginal mesh does not correlate to the clinical symptoms of vaginal pain or dyspareunia.” *Id.* at 9. These are all opinions concerning the correlations that pathologists may (or may not) make based on an examination of a specimen. Dr. Zheng, as an experienced pathology professor and practitioner, is certainly qualified to offer opinions about the limits of pathological examinations and correlations.

In essence, Dr. Zheng agrees with the concept underlying the Court’s opinion in *Huskey*: pathologists generally cannot correlate nerves, inflammation, fibrosis, or foreign body reaction with clinical symptoms of pain. The Court should exclude opinions from all pathologists—including Plaintiffs’ pathology experts—that try to make such a correlation. Since Dr. Zheng is

not offering any clinical opinions about whether meshes can cause pain, *Huskey* is inapplicable and the Court should deny Plaintiffs' Motion with respect to opinion (vi).

**C. Dr. Zheng is Especially Qualified to Offer Opinions About Whether TVT or TVT-O Mesh Causes Cancer.**

With respect to Dr. Zheng's opinion that mesh does not cause cancer, Plaintiffs again claim that this is a "materials" opinion beyond the scope of Dr. Zheng's expertise, followed by the absurd contention that "there is nothing in Dr. Zheng's profile indicating that he has the expertise to opine as to whether the TVT meshes can cause cancer." Pl.'s Mem. at 7–8. Plaintiffs' argument ignores the fact that one of the basic functions of a pathologist is the diagnosis of cancer and its causes. *See, e.g., Pritchard v. Dow Agro Sciences*, 705 F. Supp. 2d 471, 482 (W.D. Pa. 2010) (noting that pathologist was generally qualified to offer opinions about cause of plaintiff's non-Hodgkin's lymphoma), *aff'd* 430 F. App'x 102 (3d Cir. 2011); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 916 (C.D. Cal. 2004) (noting that expert's general pathology background qualified him to offer opinions about cancer and possible carcinogenicity of chemical).

Even if pathologists were not generally qualified to offer opinions on cancer and its causes, Dr. Zheng has specialized expertise allowing him to offer such opinions. Dr. Zheng has dedicated his career to studying the causes of ovarian, endometrial, and cervical cancer. Mot. Ex. C, Zheng CV, at 7–10. He has been a member of the American Association of Cancer Research since 2007 and has served on the editorial boards of the American Journal of Cancer Research, the Journal of Hematology and Oncology, the Journal of Cancer Research, and the Journal of Surgical Oncology. *Id.* at 7 & 10. He has authored or co-authored numerous publications specifically concerning carcinogenesis or tumorigenesis. *Id.* at 18–31. In forming his opinions,

he reviewed numerous studies that looked specifically at whether polypropylene meshes can cause cancer. Mot. Ex. E, Report at 10 & nn. 53–55.

In light of Dr. Zheng’s general pathology experience and specialized experience with cancer research, he is eminently qualified to opine that TVT and TVT-O do not cause cancer. The Court should deny Plaintiffs’ motion with respect to opinion (vii).

**II. The Court Should Deny Plaintiffs’ Motion with Respect to Dr. Zheng’s Response to Dr. Iakovlev.**

In his Report, Dr. Zheng offers several criticisms in response to the opinions of Plaintiffs’ pathology expert, Dr. Vladimir Iakovlev. *See* Mot. Ex. E, Report at 11–12. Plaintiffs do not challenge the opinions in Response Nos. 1, 4, and 5. Plaintiffs’ motion is limited to the statements contained in Response Nos. 2, 3, 6, and 7. The Court should deny Plaintiffs’ Motion as to the opinions expressed in these responses.

**A. Response Nos. 2 and 3 Contain Pathology Opinions Within the Scope of Dr. Zheng’s Expertise.**

In Response Nos. 2 and 3, Dr. Zheng criticizes Dr. Iakovlev’s pain opinions. Specifically, Dr. Zheng opines that Dr. Iakovlev cannot assume the presence of nerves or neural ganglia correlates to clinical complaints of pain. Mot. Ex. E, Report at 11. As with Dr. Zheng’s general opinions about correlation of pathological findings with pain, this opinion is a pathology opinion concerning the limits of pathological examination. As noted in Section I.B, *supra*, these opinions are within Dr. Zheng’s expertise as a pathologist and are not the same opinions that the Court excluded in *Huskey*.

**B. Dr. Zheng Will Not Offer Any Testimony Concerning Dr. Iakovlev’s Failure to Differentiate Between Pelvic Organ Prolapse Meshes and Stress Urinary Incontinence Meshes.**

In Response No. 6, Dr. Zheng notes that Dr. Iakovlev often fails to distinguish between pelvic organ prolapse meshes and stress urinary incontinence meshes like TVT and TVT-O.

Ethicon agrees that, in the Wave 3 cases, it will not proffer or solicit any opinions or testimony from Dr. Zheng concerning Dr. Iakovlev's failure to distinguish between different types of meshes. Plaintiff's Motion should be denied as moot with respect to Response No. 6.

**C. Dr. Zheng is Qualified to Criticize Dr. Iakovlev's Opinion That the "Bark" He Observed Was Caused by Degradation.**

In Response No. 7, Dr. Zheng criticizes Dr. Iakovlev's opinions regarding "degradation bark." Mot. Ex. E, Report at 12. Plaintiffs seize on this reference and claim that this is a "degradation" opinion and that Dr. Zheng disclaimed any expertise in materials or degradation. Mot. Ex. E, Report at 12. However, Dr. Zheng's criticism is not a "degradation" or "materials" opinion, as he used those terms at his deposition, nor do these opinions require specific expertise in biomaterials or polymer chemistry. Dr. Zheng's opinions do not go to the issue of whether Prolene does or can degrade *in vivo*. Rather, Dr. Zheng is criticizing the pathology aspects of Dr. Iakovlev's "bark" theory, including Dr. Zheng's opinion that pathological findings are consistent with degenerated collagen and Dr. Iakovlev's failure to rule out the possibility of artifacts. A pathologist like Dr. Zheng is clearly qualified to offer opinions about laboratory technique and pathology findings.

Further, Dr. Zheng's deposition testimony makes it clear that Dr. Zheng did not consider his criticism of Dr. Iakovlev's bark theory to be a "degradation" or "materials" opinion outside the scope of his qualifications:

Q. So degradation—you would consider degradation to be beyond your expertise?

A. **Overall, for this situation, yes, for this particular situation. I don't mean for everything.**

Q. So you don't intend to give any opinions about degradation in the Edwards and Huskey trials?

- A. That's not true, because Dr. Iakovlev already mentioned bark-like issues. He provide the pictures demonstrate the bark. [sic] And then based on my experience, I examined those. Then also I showed—used his same methods, like polarization versus nonpolarization conditions. Then I can't, you know, repeat his observation, then meanwhile provide my observation to that.

If he is thinking that kind of bark-like material represents degradation, then basically I can say there is no convincing evidence at all, because I can simply explain those bark-like area actually is better interpreted as degenerated collagen bundles.

Mot. Ex. B, Zheng 4/3/14 Dep. (*Huskey*) at 216:9–217:2. Dr. Zheng's criticism of Dr. Iakovlev's bark theory is properly limited to the realm of pathology, without crossing over into "materials" or "degradation" issues. Plaintiff's Motion with respect to Response No. 7 should therefore be denied.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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